GE Healthcare

Important Device Removal & Product Safety Alert

06 February 2006

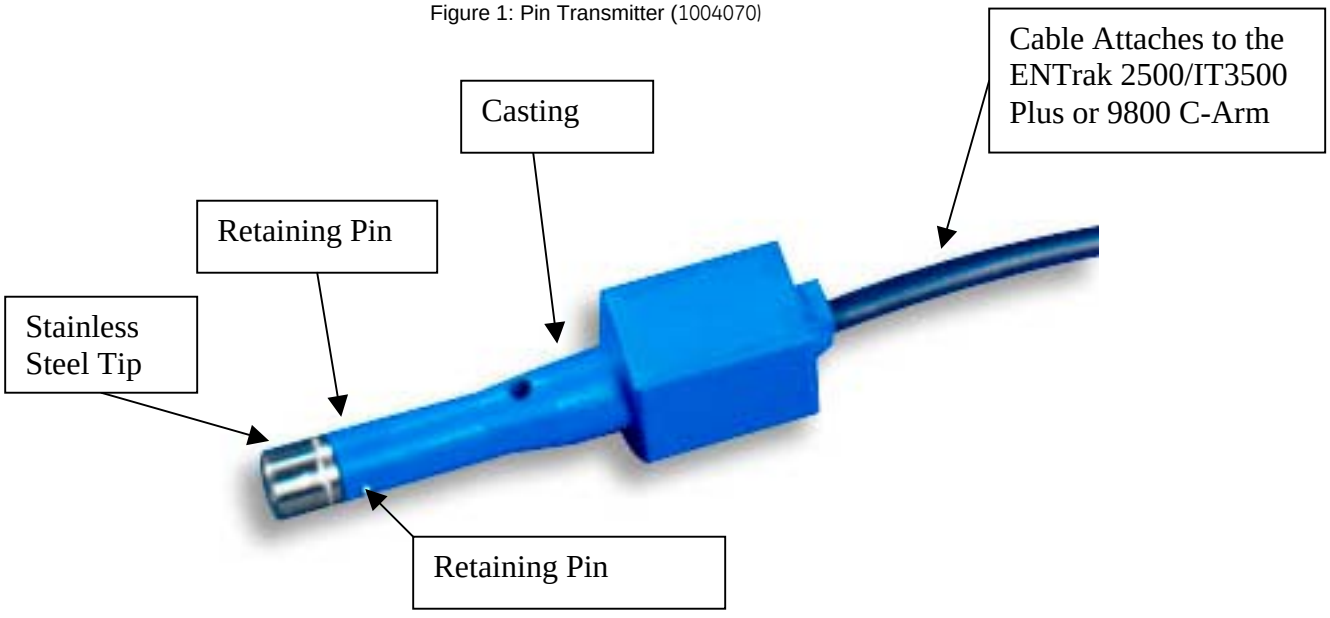
Director of Surgical Services
TBD – Hospital Name and address
TBD – Hospital Name and Address
TBD – Hospital Name and Address

Dear Healthcare Provider,

It has come to our attention that there is a potential safety concern associated with the GE Healthcare Navigation Pin Transmitter (GE P/N 1004070) that you might own. Because patient safety is of paramount concern to GE, we ask your immediate attention to help us resolve this matter.

GE Healthcare Navigation Pin Transmitter. (PN: 1004070) [See Figure 1 Below]

Figure 1: Pin Transmitter (1004070)



The housing of the Pin transmitter consists of two main parts: the casting (plastic) and the stainless steel tip that attaches the housing to the clamp/pin which is affixed to the patient (See Figure 1). The design is intended to have a small pin through each side wall of the casting to secure the stainless steel tip with two pins. In a few cases, we have seen that the stainless steel tip of the Pin Transmitter has disconnected from the casting because only one pin of the transmitter was secured. In these cases, there is a potential for this small, unattached retaining pin to fall into the surgical field.

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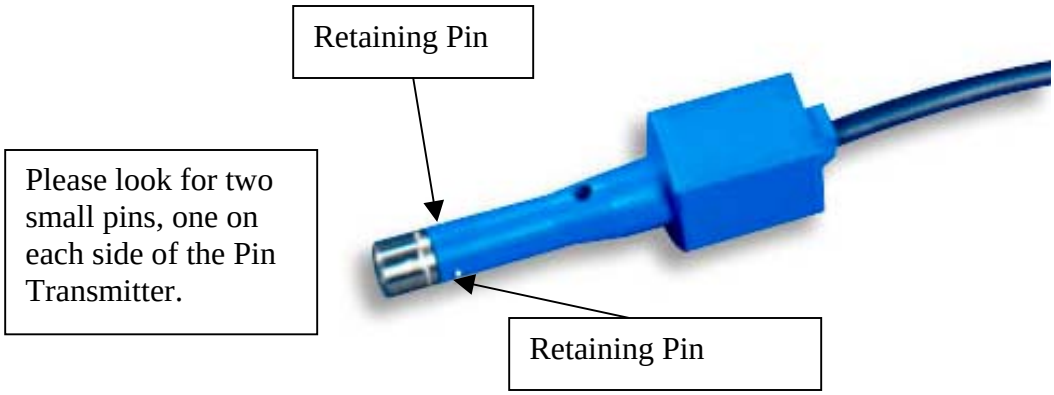
Figure 2: Pin Transmitter (1004070)



Please perform a visual inspection of your GE Healthcare Surgical Navigation Pin Transmitter (PN: 1004070) to make sure that your Pin Transmitter is pinned on both sides of the transmitter (See Figure 2) and follow the instructions below:

If you have a defective Pin Transmitter (pin on one side only):

1) Please discontinue the use of the Pin Transmitter and contact GE Healthcare Customer Service at (800) 874-7378 option 1 to arrange for a part replacement. You may fill out the attached form and FAX it to GE Healthcare Customer Service to help expedite the replacement of the Pin Transmitter.
2) Please convey this information to your OR management along with all users of the ENTrak 2500 Plus, InstaTrak 3500 Plus, or 9800 C-Arm Navigation Systems.

If your Pin Transmitter is not defective (pinned on both sides), you may continue to safely use this device. We simply ask that you contact GE Healthcare Customer Service at (800) 874-7378 option 1 and confirm your inspection with us. You may fill out the attached form and fax it back to GE Healthcare Customer Service at your first available opportunity.

If you have an affected Pin Transmitter, we plan to replace it as soon as possible at no cost to you. A GE Surgery Field Service Engineer will be contacting you to arrange for a part replacement which will enable you to continue using your ENTrak 2500 Plus, IT 3500 Plus and 9800 C-Arm Navigation Systems.

GE appreciates your awareness and cooperation in order to remedy this potential health concern. If you have any questions please contact GE Healthcare Customer Service at (800) 874-7378 option 1.

Sincerely,

Kenneth F. Miles, Ph.D.

Kenneth F. Miles, Ph.D.
GE Healthcare - Interventional Cardiology & Surgery
V.P. Quality & Regulatory

GE Healthcare

Pin Transmitter Request Form

Facility:

Contact:

Part Replacement: GE Healthcare Surgical Navigation Pin Transmitter (PN: 1004070)

Please select **one** of the following:

☐ I have inspected my GE Healthcare Surgical Navigation Pin Transmitter (PN: 1004070) and it **does require** replacement.

☐ I have inspected my GE Healthcare Surgical Navigation Pin Transmitter (PN: 1004070) and it **does NOT** require replacement.

Printed Name: _____

Date: _____

Please FAX to: (801) 521-3903